REMARKS

The final Office action mailed June 23, 2006 has been received and reviewed. All pending claims stand rejected. The application is to be amended as previously set forth. All amendments and claim cancellations are made without prejudice or disclaimer. Reconsideration is respectfully requested.

A. 35 U.S.C. § 112

Claims 9, 10, 16 and 17 were rejected under the second paragraph of 35 U.S.C. § 112 as assertedly being unclear. Claims 9 and 10 are to be canceled, thus mooting the rejection as to them. Applicants have amended claims 16 and 17, and, in view of the amendments, request that the rejection be withdrawn.

Specifically, "the viral RNA" terminology of claims 16 and 17 were identified as not having sufficient antecedent basis. The terminology is to be amended to – nucleic acid of interest--, which should overcome the rejection.

B. 35 U.S.C. § 102

Claims 2-4, 6, 7, 9, 10, 14, 16, and 17 were rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Cassol et al. Claims 9 and 10 are to be canceled, thus mooting the rejection as to them. Applicants traverse the remainder of the rejection.

Cassol et al. is not believed to disclose a method according to independent claim 2 since, among other things, Cassol et al. does not quantify the nucleic acid of interest present in the sample, which is element (f) of claim 2.

Instead, Cassol et al. is concerned about genetic characterization of HIV. Cassol et al. monitors genetic evolution and establishes genetic variation. More particularly, Cassol et al. is concerned about drug-resistance mutations in the genome of HIV. In order to analyze the occurrence of such mutations, a sequencing protocol is used wherein dried blood is analyzed. As shown in Cassol et al., on page 353, first column, second paragraph (with the heading "Screening for ZDV resistant mutations"), dried blood appeared to be useful for the rapid identification of mothers and infants with significant levels (> 10%) of resistance mutations. Five known ZDV-associated mutations were semi-quantitatively detected using two different sequencing reactions. What was thus determined was what kinds of mutations occurred most frequently, relative to one

another. Subsequently, Cassol et al. concluded that the mutation ACC to TAC or TTC at amino acid 15 is the most common mutation.

However, determining what mutation occurs most frequently is not the same as quantifying how much nucleic acid is present in a sample. Cassol et al. qualitatively determines the occurrence of mutations and determines which mutations occur most often relative to one another, but Cassol et al. does not measure the total amount of HIV nucleic acid present in a sample. Hence, Cassol et al. does not determine viral nucleic acid concentration in blood. The stage of disease thus cannot be determined with a method such as that disclosed by Cassol et al.

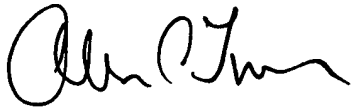
In conclusion, Cassol et al. does not quantify the amount of HIV nucleic acid present in a sample. Cassol et al. only determines what kinds of mutations occur in a population. This is made clear by Cassol et al. at page 354, first column, third paragraph, first sentence:

> "The ability to sequence the C2V3 region directly from DBS specimens would allow for the characterization of large numbers of variants involved in maternal-child transmission." (Emphasis added).

The current set of claims is thus thought to sufficiently distinguish Cassol et al.

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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